UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON. INC.; and ETHICON LLC, Defendants.	Case No. 2:20-cv-01232-KJD-VCF ORDER

Presently before the Court is Plaintiffs' Motion to Exclude Opinions and Testimony of Timothy Ulatowski (#189). Defendant filed a response in opposition (#213).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices– Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Ulatowski holds a master's degree in physiology and a bachelor's degree in microbiology. A thirty-seven (37) year Food and Drug Administration ("FDA") employee, Mr. Ulatowski now provides regulatory consulting services regarding premarket, postmarket, and compliance for

FDA-regulated medical devices. He is not a doctor, a materials scientist, nor a chemical engineer. He "specializes in medical device regulations, policies, and procedures administered by the Food and Drug Administration."

Plaintiffs note that Judge Goodwin previously entered an order in the MDL proceedings excluding most of Ulatowski's opinions (Doc. No. 148-11). Plaintiffs argue that the Court should follow Judge Goodwin's order and exclude all opinion testimony regarding the FDA 510(k) clearance process, or other regulatory issues, because what little probative value they have is outweighed by danger of confusing the jury and causing undue prejudice to Plaintiffs by implying that adherence to regulatory standards absolves Defendant of liability. Plaintiffs also urge the Court to exclude Ulatowski's opinion that Ethicon's risk management policies substantially complied with regulations and industry standards. Defendant disagrees.

II. Analysis

A. Legal Standard

Federal Rule of Evidence ("Rule") 702 permits a "witness who is qualified as an expert by knowledge, skill, experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." The Supreme Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed "a special obligation upon a trial judge to 'ensure that any and all scientific testimony… is not only relevant, but reliable.'" See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this gatekeeping obligation to all expert testimony. Id. at 147. Daubert "established that, faced with a proffer of expert scientific testimony, the trial judge, in making the initial determination whether to admit the evidence, must determine whether the expert's testimony reflects (1) "scientific knowledge," and (2) will assist the trier of fact to understand or determine a material fact at issue." Daubert, 509 U.S. at 592. The "focus must be solely on principles and

methodology, not on the conclusions that they generate." Id. at 595.

The Ninth Circuit has emphasized that "Rule 702 is applied consistent with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barrier to opinion testimony." Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). "An expert witness–unlike other witnesses–is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation, so long as the expert's opinion [has] a reliable basis in the knowledge and experience of his discipline." Id. (citations and quotation marks omitted).

In Daubert, the Court also clarified that parties should not be "overly pessimistic about the capabilities of the jury and of the adversary system generally." Daubert, 509 U.S. at 596. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. "The role of the Court is not to determine 'the correctness of the expert's conclusions but the soundness of his methodology.'" Great W. Air, LLC v. Cirrus Design Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). "The judge is supposed to screen the jury from unreliable nonsense opinions… [t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." Id. at 4.

B. Section 510(k) Testimony

Judge Goodwin has previously ruled that evidence regarding the FDA's section 510(k) process is of no or negligible relevance and its probative value is substantially outweighed by the risk of unfair prejudice, misleading the jury, confusing the issues, and wasting time. See Doc. No. 148-11; Bellew v. Ethicon, Inc., No. 2:13-CV-22473, 2014 WL 6680356, at *10 (S.D.W. Va. Nov. 25, 2014). He therefore excluded Ulatowski's opinions regarding the section 510(k) process, "including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application." ECF No. 148-11 at 6-7. He also excluded Ulatowski's opinions "about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations." Id. at 7. Judge Goodwin reserved ruling on Ulatowski's

opinions regarding Ethicon's compliance with design control and risk management standards "whether rooted in the FDA or otherwise." Id. at 8. The Fourth and Eleventh Circuits have affirmed his ruling in similar contexts. See Kaiser v. Johnson & Johnson, 947 F.3d 996, 1018 (7th Cir. 2020); Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1318 (11th Cir. 2017); In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913, 920-23 (4th Cir. 2016).

The Court, having extensively reviewed the case law cited by Defendant, sees no reason to reconsider these decisions. Sch. Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc., 5 F.3d 1255, 1263 (9th Cir. 1993). Even if section 510(k) evidence has some relevance to the merits of Carter's claim or her request for punitive damages, this type of evidence presents "the very substantial dangers of misleading the jury and confusing the issues," as well as wasting time in what is already likely to be a lengthy trial. In re C.R. Bard, Inc., 810 F.3d at 922. Section 510(k) evidence would "subject[ ] the jury to many hours, and possibly days, of complex testimony about regulatory compliance" that "could lead jurors to erroneously conclude that regulatory compliance proved product safety." Id. Such a " 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it," whether the defendants' product was unreasonably dangerous. Id. "While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific," because section 510(k) clearance "does not amount to a safety regulation requiring device producers to meet any established design standards." Id. at 921-22; see also Kaiser, 947 F.3d at 1018 ("Simply put, Prolift's § 510(k) clearance is remote from FDA safety review.").

This is not to say that the section 510(k) evidence is never admissible. Were Plaintiffs to put at issue Defendant's compliance with section 510(k) or other FDA regulations, then Ulatowski's opinions could be admissible to rebut such assertions.

Therefore, the Court grants Plaintiffs' motion to exclude Ulatowski's opinions about section 510(k).

C. Compliance with Regulations and Industry Standards

In response to Plaintiffs' arguments that Ulatowski should not be allowed to offer his opinion that "Ethicon's risk management policies substantially complied with regulations and industry standards[,]" Defendant asserts that it will only introduce evidence of compliance with the regulations if Plaintiffs' expert opines that Ethicon did not comply with regulations. Ulatowski is qualified to offer an opinion on compliance. However, it may only be offered if Plaintiffs' expert testifies that Defendant was not in compliance.

III. Conclusion

Accordingly, **IT IS HEREBY ORDERED** that Plaintiffs' Motion to Exclude Opinions and Testimony of Timothy Ulatowski (#189) is **GRANTED** in part and **DENIED** in part.

DATED this 29th day of September 2022.

Kent J. Dawson
United States District Judge